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10/809,811	03/26/2004	Nagaraja Rao Ramesh Mysore	US 1375/04	7940

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Law Office - Dinesh Agarwal, P.C.
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Alexandria, VA 22312

EXAMINER

SCHUBERG, LAURA J

ART UNIT	PAPER NUMBER
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1657

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,811	Applicant(s) MYSORE ET AL.	
	Examiner LAURA SCHUBERG	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-20, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 and 26-27 are pending.

Claim 9 was withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/09/2007.

Claims 21-25 have been canceled.

Claims 1, 8, 10, 19, 20 and 27 have been amended.

Claims 1-8, 10-20, 26 and 27 have been examined on the merits.

Response to Arguments

Applicant's arguments filed 12/18/2007 have been fully considered but they are not persuasive.

Applicant argues with regard to the 102(b) rejection that Sangeetha et al only attempt to study the effect of reaction conditions on FOS production, without studying the effect of chosen variables on the functional properties of FOS.

This is not found persuasive because the Sangeetha et al reference teaches all the same method steps as the claimed invention and therefore anticipates the claimed invention. According to MPEP 2131.04, a reference may be directed to an entirely different problem than the one addressed by the inventor, yet still be anticipatory if it explicitly or inherently discloses every limitation recited in the claims.

Applicant argues that Sangeetha et al use sucrose as a sole source of carbon, whereas, the present invention uses jaggery in addition to sucrose.

This is not found persuasive because claim 10 recites that “the substrate is selected from the group consisting of sucrose, jaggery, ...” and is interpreted as a Markush claim requiring either sucrose or jaggery as the substrate, but not both. Therefore a reference is anticipatory if either sucrose or jaggery is included as the substrate.

Applicant argues with regard to the obviousness rejection that Sangeetha et al and Vijayendra et al are cited with respect to the strains of *Aureobasidium pullulans* and that the claimed invention is directed to the use of *Aspergillus oryzae* and *Aspergillus pullulans*. Applicant argues that the references do not suggest the use of jaggery as the substrate for *Aspergillus oryzae* and *Aspergillus pullulans*.

This is not found persuasive because this obviousness rejection is with regard to claims 1 and 10, which do not require a specific strain of culture, only that the culture used be capable of producing FTase, which it does.

Applicant argues with regard to the obviousness rejection that Brouwers is silent on the use of adding stevia to a FOS preparation. Applicant asserts that FOS and GOS are different and the addition of stevia to GOS would not suggest adding stevia to FOS.

This is not found persuasive because Brouwers specifically suggests the combination of stevia and GOS with FOS (page 2 para 21) as well as the fact that stevia has no pronounced effect on the activity of sugar-metabolizing enzymes (page 2 para 28). The advantage of optimal control of sweetness is taught (page 1 para 6) and is sufficient to motivate one of ordinary skill in the art to add stevia to FOS since it is used as a food additive as well. Since stevia does not affect the activity of FTase or GTase,

one of ordinary skill in the art would have had a reasonable expectation of success in enhancing the sweetness without interfering with the product production of the sugar metabolizing enzyme. In addition, stevia is recited as optional in claim 10 and is therefore not a requirement of the claimed invention.

Applicant argues with regard to the obviousness rejection that Jonniaux et al is limited to the recombinant strain of *Aspergillus oryzae* and that the present application uses *Aspergillus oryzae* that inherently expresses FTase.

This is not found persuasive because the claims rejected under Jonniaux et al (claims 26 and 27 which are dependent upon claims 1, 4 and 6) do not require that the strain not be a recombinant host.

Applicant argues that the method of recycle/immobilization described by Jonniaux et al is distinct from the recycle method described in the present application.

This is not found persuasive because the invention as claimed does not require a specific recycle method, only that the culture be recycled in some way.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "any pellets" in line 6. There is insufficient antecedent basis for this limitation in the claim because there is no mention of the addition or use of pellets prior to discarding them in line 7 of claim 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sangeetha et al (Sciences Des Aliments 2002).

Claim 1 is drawn to a process for obtaining FOS comprising: a) growing a culture in a medium at 5-6 pH, 25-30 degrees C under stirring conditions to obtain an inoculum, b) transferring the inoculum to a medium under fermentation conditions to obtain FTase, c) incubating the FTase with 400-800 g/L of a substrate at pH 5 to 5.5 for 18 to 24 hours at 50 to 55 degrees C and d) optionally along with additives to improve quality of FOS.

Claim 2 includes wherein the medium in step a) consists of sucrose in the range of 0.8 to 1.5% and yeast extract in the ranges of 0.1 to 0.5 %.

Claim 3 includes wherein the stirring in step a) is done at 200 to 250 rpm for 24-48 hours.

Claim 4 includes wherein the culture used in step a) is selected from the group consisting of *Aspergillus oryzae* and *Aspergillus pullulans*, capable of producing FTase.

Claim 5 includes wherein the inoculum used is developed from 5 to 8 days old slant culture.

Claim 6 includes wherein the FTase is prepared by fermentation process selected from the group consisting of submerged fermentation and solid state fermentation (Applicant elected submerged fermentation).

Claim 7 includes wherein the predetermined concentration of the inoculum varies in the range of 10 to 25% (v/v) for submerged fermentation.

Claim 10 includes wherein the substrate is selected from a group consisting of sucrose, jaggery optionally along with stevia extract as an additive to improve sweetness.

Claims 11 and 12 include specific concentrations for the stevia extract.

Claims 13 and 14 include wherein the sweetness in FOS is increased a specific amount.

Claims 15-20 include functional properties of the FOS produced.

Sangeetha et al teach a method for the production of FTase and FOS and the influence of media components and reaction parameters. A culture of *Aspergillus oryzae* was prepared by transferring spores from a 5 day old slant to medium containing

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1% sucrose and 0.2% yeast extract at pH 5.5 and incubated at 30 degrees C on rotary shaker (stirring conditions) at 250 rpm for 24 hours (page 279 part 2.2) to produce FTase. Submerged fermentation is taught (page 279 part 2.3 and page 286 line 6) as well as discarding the pellets after filtering the culture broth to obtain FTase and wherein the concentration of the inoculum is 10% (page 281 table 1). FOS production was carried out by incubation of the FTase with sucrose as the substrate (page 280 part 2.5). Since the FOS yields are 21.5g/L to 435.68 g/L corresponding to 4.3% to 54.46% (w/w) of the initial sucrose, respectively, the concentration of the substrate (sucrose) ranged from 400 to 800 g/L (page 282 part 3.1). Sangeetha et al teach wherein the pH of the substrate and the medium is 5.5, wherein the reaction time is 18 hours and wherein the temperature is 55 degrees C (page 281 table 1).

While the reference does not specifically teach the functional properties of the FOS produced (as cited in claims 15-20), these properties are deemed inherent since the production method of the reference FOS has the same steps as the claimed method.

All limitations indicated as optional, such as additives and stevia extract (claims 1 and 10-14), are not required for the method as claimed.

Therefore, the teachings of Sangeetha et al anticipate Applicant's invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002).

Claim 8 includes specific concentrations for the submerged fermentation medium and specific incubation and temperature ranges followed by discarding the pellets after filtering the culture broth to obtain FTase.

Sangeetha et al teach a method for the production of FTase and FOS as described above.

Submerged fermentation is taught (page 279 part 2.3 and page 286 line 6) as well as discarding the pellets after filtering the culture broth to obtain FTase and wherein

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the concentration of the inoculum is 10% (page 281 table 1). Wherein the submerged fermentation medium consists of sucrose at 10%, yeast extract at 0.8%, $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ at 0.02%, NaNO_3 at 1.0 and 3.0%, KH_2PO_4 at 0.5 %, K_2HPO_4 at 0.5%, NaCl at 0.5%, NH_4Cl at 1.0% and incubated for 48 to 120 hours (page 281 table 1) at a temperature of 30 degrees C (page 279 part 2.3) is taught.

Sangeetha et al do not specifically teach the concentration range of 0.8-1.0% of K_2HPO_4 in the submerged fermentation medium.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Therefore it would have been a matter of routine optimization for one of ordinary skill in the art to use the concentration range of 0.8-1.0% of K_2HPO_4 in the submerged fermentation medium of Sangeetha et al. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to optimize the result effective variable of quality and quantity of product produced.

Therefore the teaching of Sangeetha et al renders obvious Applicant's invention as claimed.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) as applied to claims 1-7, 10-20 above, and further in view of Vijayendra et al. (Process Biochemistry 2001).

Claim 10 includes wherein the substrate is selected from a group consisting of sucrose, jaggery optionally along with stevia extract as an additive to improve sweetness.

Sangeetha et al teach the process for obtaining FOS as described above, but does not specifically mention using jaggery as the substrate. Sangeetha does teach that *Aureobasidium pullulans* is also a suitable microbial source for production of FTase and FOS (page 278 part 1 paragraph 3).

Vijayendra teaches jaggery is a suitable substitute for sucrose in the fermentation of *Aureobasidium pullulans* (page 262 part 4) and that jaggery is a good carbon source to support the growth as well as the production of byproducts (page 361 part 3.2).

Therefore, it would have been obvious to substitute jaggery for sucrose as the substrate in the method of Sangeetha et al because Vijayendra et al teach that jaggery is a suitable substitute for sucrose as a carbon source for *Aureobasidium pullulans*. One of ordinary skill in the art would have been motivated with a reasonable expectation of success because Sangeetha et al teach that *Aureobasidium pullulans* may also be used to produced Ftase and FOS and Vijayendra et al teach that *Aureobasidium pullulans* grows well with jaggery.

Therefore, the combined teachings of Sangeetha et al and Vijayendra et al render obvious Applicant's invention as claimed.

Claims 1 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) as applied to claims 1-8, 10-20 above, and further in view of Brouwers (US 2002/0065245).

Sangeetha et al teach the process for obtaining FOS as described above, but does not specifically mention the addition of stevia extract to the substrate and Ftase. Sangeetha et al teach that FOS finds numerous applications such as beverages and food products (page 278 part 1).

Brouwers teaches that FOS (page 2 para 21) and stevia extract are suitable additions to a composition that is ideal for food products for sweetening and extension of storage life. Brouwers teaches that the addition of stevia extract to gluco-oligo-saccharides provides a composition with an improved taste and improved digestive qualities. Another advantage is the stability of the final product, which is heat resistant and has an adjustable sweetening proportion per volume-unity (page 1 para 8). Brouwers also teaches that stevia has no pronounced effect on the activity of principal sugar-metabolizing enzymes and this was tested by measuring the enzyme activities with the natural substrates and in the presence of varying concentrations of stevia (page 2 para 25-28).

Therefore, one of ordinary skill in the art would have been motivated to add stevia extract to the substrate in the method of Sangeetha et al because Brouwers teaches that the addition of stevia extract provides numerous advantages such as improved taste, digestive qualities, extension of storage life and heat resistance. One of

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ordinary skill in the art would have also been motivated by Sangeetha's teaching that FOS is used for beverages and food products that would also benefit from these advantages and that Brouwers teaches that FOS is a sugar with a low sweetening capacity that is suitable for combination with stevia. One of ordinary skill in the art would have had a reasonable expectation of success in adding stevia to the substrate because Brouwers teaches that stevia has no pronounced effect on the activity of principal sugar-metabolizing enzymes and this was tested by measuring the enzyme activities with the natural substrates and in the presence of varying concentrations of stevia (page 2 para 25-28). The lowering of the concentration of stevia extract to 1% would have been a matter of routine optimization, the ordinary artisan realizing that in some situations compositions wherein the increase in sweetness is about 36 to 40% would be desired.

Therefore, the combined teachings of Sangeetha et al and Brouwers render obvious Applicant's invention as claimed.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) as applied to claims 1-8, 10-20 above, and further in view of Jonniaux et al (US 6,518,047).

Claim 26 includes wherein the culture is recycled for production of FOS.

Claim 27 includes wherein the culture is recycled at least 6 times for production of FOS.

Sangeetha et al teach the process for obtaining FOS as described above, but does not specifically mention recycling the culture for production of FOS.

Jonniaux et al teach that whole cells, cell extracts, cell-free extracts, enzyme preparations or purified enzymes may be immobilized by any conventional means to allow for recycling (column 6 lines 46-63). *Aspergillus oryzae* is taught as one of the cultures used for the enzyme preparation (column 1 lines 26-35).

Therefore, one of ordinary skill in the art would have been motivated to recycle the culture of *Aspergillus oryzae* in the method of Sangeetha et al because recycling of the culture would have allowed for the most efficient use of resources and Jonniaux et al teach that it is known to do this for enzyme or cell preparations. The number of times for recycling would have been a matter of routine optimization. One of ordinary skill in the art would have had a reasonable expectation of success because Jonniaux et al teach that *Aspergillus oryzae* is a suitable culture for recycling.

Therefore, the combined teachings of Sangeetha et al and Jonniaux et al render obvious Applicant's invention as claimed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Leon B Lankford, Jr
Examiner
Art Unit 1651

Laura Schuberg